In response to the Office Action of August 24, 2005

Serial No. 10/727,006

<u>REMARKS</u>

Summary of the Office Action

In the Office Action, the Examiner rejected Claims 1-14 and 17-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,463,751 issued to Bledsoe (hereinafter "BLEDSOE") in view of U.S. Patent No. 5,997,493 issued to Young (hereinafter "YOUNG"). Additionally, the Examiner rejected Claims 15, 16 and 21 under 35 U.S.C § 103(a) as being unpatentable over BLEDSOE, YOUNG and in view of U.S. Patent No. 4,523,585 issued to Lamb et al. (hereinafter "LAMB"). Furthermore, the Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter of Claim 4. Finally, the Examiner indicated that the specification fails to provide proper antecedent basis for the claimed subject matter of Claim 1 and requests appropriate correction.

Antecedent Basis Objection - Claim 4

The Examiner indicated that the specification failed to provide proper antecedent basis for the claimed subject matter of Claim 4 wherein the specification on Page 13, Lines 4-5 recited "flexion-extension regulating device 24 is formed by attaching an upper member 26 and a lower member 28 together" fails to provide proper antecedent basis to the claim limitation of Claim 4 recited as "unitarily formed to each other." (Office Action, Page 10).

In a telephone conversation on October 31, 2005 between Applicant's representative and Examiner Ali, Applicant's representative pointed out to the Examiner that the above noted objection regarding Claim 4 was previously addressed in a Response to the Office Action of March 8, 2005 wherein Applicant amended paragraph 32 to include the sentence: "additionally flexion-extension regulating device 24 may also be formed with the upper and lower members 26, 28 being unitarily formed to each other." After learning of the above noted amendment to the specification in response to the March 8, 2005 Office Action, the Examiner then indicated that such amendment was properly responsive to the objection such that no further amendments were necessary in the present Office Action dated August 24, 2005 with regard to the antecedent basis objection of Claim 4.

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Antecedent Basis Objection - Claim 1

In the Office Action, the Examiner objected to the specification for failing to provide proper antecedent basis for the claimed subject matter of Claim 1 wherein the Examiner indicated that the specification did not positively recite "connectable to the lower strut" as is recited in Claim 1. The Examiner indicated that the disclosure on Page 6, Paragraph 13 states "a motion limiting member is pivotally connected [to the lower member]...it is further pivotally *connectable* to an end portion of the knee brace's lower strut." (Office Action, Page 11).

By this paper, Applicant has amended independent Claims 1 and 17 to recite that the "motion limiting member...[is] pivotally *connected* to the end portion of the lower strut" such that the objection to the specification regarding lack of antecedent basis for Claim 1 is now believed to be overcome.

Traversal of Rejection Under 35 U.S.C. § 103(a) – Independent Claims 1 and 17

Applicant traverses the rejection of independent Claims 1 and 17 under 35 U.S.C. § 103(a) as being unpatentable over BLEDSOE in view of YOUNG.

BLEDSOE is directed to a stabilizing knee hinge that interconnects rigid femoral and tibial arms 12, 14, respectively. The hinge comprises a pair of generally circular stop limit plates 48, 50 that are rotatably mounted within two femoral joint element plates 42, 44. The hinge further includes a pair of tibial plates 66, 68 that are pivotally mounted in spaced parallel relationship to one another and which are disposed on outer sides of the femoral plates 42, 44. The femoral plates 42, 44 are understood to be *rigidly* (i.e., non-pivotally) connected to the femoral arm 12, as will be discussed in greater detail below. Likewise, the tibial plates 66, 68 are also understood to be *rigidly* (i.e., non-pivotally) connected to the tibial arm 14, as will also be discussed in greater detail below.

The specification of BLEDSOE is understood to teach that the femoral plates 42, 44 are disposed in spaced, parallel relationship to one another and that the stop limit plates 48, 50 are rotatably mounted between the femoral plates 42, 44. Additionally, the femoral plates 42, 44 and the stop limit plates 48, 50 are rotatably mounted or secured together utilizing a

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pivot 46. The femoral plates 42, 44 include two arcuate cam slots 58, 60. "Pivot and bearing pins 70 and 72 are mounted to arcuate cams slots 58 and 60 respectively and serve to pivotally mount tibial plates 66 and 68 to femoral plates 42 and 44." BLEDSOE, column 3, lines 55-58. As understood, it is the connection between the tibial plates 66, 68 and the femoral plates 42, 44, that BLEDSOE utilizes in order to imitate the polycentric movement of the knee.

In this regard, BLEDSOE is understood to teach a "twin cam approach" that is intended to approximate the motion of the human knee through the use of a pivotal connection between the femoral plates 42, 44 and the tibial plates 66, 68 mentioned above. In this regard, BLEDSOE teaches that "the pivoting of the tibial arm 14 will cause pivot and bearing pins 70 and 72 to track clockwise to arcuate cam slots 58 and 60, permitting tibial plates 66 and 68 to pivot with respect to femoral plates 42 and 44." (BLEDSOE, column 3, lines 58-62).

BLEDSOE is also understood to teach that the pivot and bearing pins 70, 72, as shown in Figure 2, which reside in arcuate cam slots 58, 60, limit the range of motion of the hinge. More specifically, the stop limit plates 48, 50 are operative to restrict the range of motion of the pivot and bearing pin 70, 72 within the arcuate cam slots 58, 60. By limiting the range of motion of the pivot and bearing pins 70, 72, the hinge can thereby limit the range of motion of a stabilized knee.

Independent Claim 1

Applicant's amended independent Claim 1 now recites "a motion limited member being pivotally connected to the end portion of the lower strut."

In the Office Action, the Examiner indicates that the motion limiting member of Applicant's invention is present in BLEDSOE. In particular, the Examiner indicates that BLEDSOE has "a motion limiting member (See Fig. 5 reference object 68) connectable (See Fig. 5, connectable via reference object 46) to the end portion of the lower strut (See Fig. 4 with end portion located near reference objects 40 and 38), . . ." The Examiner then indicates that while BLEDSOE "does not disclose the [motion limiting] member being pivotally

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connected to the lower member and further being pivotally connect[ed] to the end portion of the lower strut", such "limitation is taught by Young US 5,997,493."

More specifically, the Examiner indicates that "Young teaches a hinge for use in an orthopedic brace with second hinge member/locking plate (Fig. 3, 1008) ("motion limiting member"), where a plate having a projection/flange (Fig. 3, 1088) which prevents relative movement of the hinge member in a given direction." The Examiner further indicates that Young "teach [that] the flange is moveable ('pivotal') (the flange inherently considered to move along the arcuate path...) along the arcuate slot and one end of the plate is connecting to a strut via rivets (Fig. 1, 106-108)." (Office Action Pages 3-4). The Examiner further indicates that "it would have been obvious... to modify the motion limiting member of Bledsoe in view of Young in order to provide a pivotal member which is connected to the lower member and further connected to the lower strut..."

While Applicant agrees with the Examiner that BLEDSOE's motion limiting member is not pivotally connected to the lower member and further is not pivotally connected to the lower strut, Applicant respectfully asserts that YOUNG fails to teach such limitation. For example, the Examiner indicates in the Office Action that YOUNG discloses locking plate 1008 as being the structural and functional equivalent of the motion limiting member of Applicant's invention. Applicant agrees with this assertion as YOUNG discloses that the locking plate 1008 is "adapted, by the provision of a central circular hole...1014...to receive slidingly, pivotal and securing means in the form of pivot bolts 1018" such that the locking plate 1008 appears to be pivotally connected to the housing 1022 (the structural equivalent of the lower member of Applicant's invention). (YOUNG, Col. 5, Lines 16-29; Figs. 1 & 3).

However, as can be seen in Figure 1 of YOUNG, the structural equivalent of the lower strut appears to be rigidly and non-pivotally connected to the structural equivalent of the motion limiting member. More specifically, YOUNG discloses that "brace [arm] 101...[is] secured to a left locking plate stub arm 1002...by rivet means 108." (YOUNG; Fig. 1; Col. 5, Lines 5-7). As can be seen in Figure 3 of YOUNG, the left locking plate stub arm 1002 is integrally formed with locking plate 1008. Therefore, Applicant respectfully asserts that the connection between the left locking plate stub arm 1002 and the locking plate 1008 is non-pivotal.

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Furthermore, nowhere in the drawings or the specification of YOUNG is it indicated or illustrated that a pivotal relationship was intended to be created between the locking plate 1008 (the structural equivalent of the motion limiting member) and the brace arm 1002 (the structural equivalent of the lower strut). Therefore, Applicant respectfully submits that YOUNG does not appear to teach or suggest the feature of the motion limiting member being pivotally connected to the end portion of the lower strut as claimed in amended independent Claim 1. Likewise, neither BLEDSOE nor the combination of BLEDSOE and YOUNG, appear to teach such feature.

Applicant submits that because BLEDSOE and YOUNG, taken either alone or in combination, fail to teach each and every element as claimed in amended Claim 1, a *prima facia* case of obviousness is not established and the rejection is therefore traversed. For this reason, independent Claim 1 is believed to be patentable over the cited and applied references. Likewise, all Claims depending from independent Claim 1, namely Claims 1-16, are also believed to be allowable as they are dependent upon an allowable base claim.

Independent Claim 17

Applicant's amended Claim 17 recites "a motion limiting member engaged to the reflection extension regulating device and being pivotally connected to the end portion of the lower strut."

Claim 17 incorporates claim language similar to independent Claim 1 and Applicant therefore asserts that Claim 17 is patentable because neither BLEDSOE nor YOUNG, either individually or in combination, disclose each and every feature of the invention. More specifically, neither BLEDSOE nor YOUNG teach a feature common to both Claims 1 and 17, namely, that the motion limiting member is pivotally connected to the end portion of the lower strut. For these reasons and those detailed above, Applicant submits that the Examiner has failed to establish an adequate evidentiary basis sufficient to support a rejection of obviousness under 35 U.S.C. § 103(a). Therefore, Applicant submits that the Examiner's rejection of Claim 17 should be withdrawn. Likewise, all Claims depending from independent Claim 17, namely Claims 18-21, are also believed to be allowable as they are dependent upon an allowable base claim.

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Traversal of Rejection Under 35 U.S.C. § 103(a) - Claims 15, 16 and 21

Applicant traverses the rejection of Claims 15, 16 and 21 under 103(a) as being unpatentable over BLEDSOE, YOUNG and further in view of U.S. Patent No. 4,523,585 (hereinafter "LAMB").

Claims 15 and 16 depend from independent Claim 1 and recite additional features that further define the present invention embodied in Claim 1. Therefore, for the same reasons discussed above, BLEDSOE and YOUNG, either individually or in combination, fail to teach or suggest at least the above-noted features of the instant invention as recited in Claim 1. Therefore, Applicant respectfully submits that Claims 15 and 16 are allowable at least for the reason that they depend from an allowable base claim and because they recite additional features that further define the present invention. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 15 and 16 under 35 U.S.C. § 103(a) and indicate that these claims are allowable over the art of record.

Claim 21 depends from independent Claim 17 and recites additional features that further define the present invention embodied in Claim 17. For the same reasons discussed above, BLEDSOE and YOUNG, either individually or in combination, fail to teach or suggest at least the above-noted features of the instant invention as recited in Claim 17. Therefore, Applicant respectfully requests that the rejection of Claim 21 under 35 U.S.C. § 2103(a) be withdrawn. Furthermore, Applicant submits that Claim 21 is allowable at least for the reason that it depends from an allowable base claim and because it recites additional features that further define the present invention. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claim 21 under 35 U.S.C. § 103(a) and indicate that this claim is allowable over the art of record.

CONCLUSION

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability and respectfully requests the Examiner to indicate allowance of each and every pending claim of the present invention.

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In view of the foregoing, it is submitted that none of the references of record, when considered individually or in any proper combination thereof, anticipate or render obvious the Applicant's invention as recited in each of Claims 1-21. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

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